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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/611,835	07/07/2000	Brent R. Stockwell	50164/002002	6924

21559 7590 07/17/2003

CLARK & ELBING LLP  
101 FEDERAL STREET  
BOSTON, MA 02110

EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 07/17/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/611,835

Applicant(s)

STOCKWELL ET AL.

Examiner

My-Chau T. Tran

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 89-156 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 89-156 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

**Note:** The examiner for your application in the PTO has changed. However, the Group and/or Art Unit location of your application in the PTO is remained the same, which is Group Art Unit 1639.

#### ***Response to Amendment***

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.
2. Claims 89-156 are pending in the present application and treated on the merit in this Office Action.

#### **Withdrawn Rejections**

3. The previous rejections 35 USC 112, first paragraph (written description and overbreadth/lack of enablement), for claims 86-156 have been withdrawn in view of applicant's arguments and telephonic interview with Andrew Wang (SPE).

#### ***Maintained Rejections***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

5. Claims 89-153 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (new matter). The newly added claims recite that the effect of the combination of compounds on the biological property of the test cells is “*qualitatively or quantitatively superior to the effect of each compound, individually, on said biological property of the test cells.*” The disclosure does not appear to support the introduction of this claim limitation. Applicants have not indicated where support for this limitation can be found in the application as filed. In accordance with MPEP 714.02, applicant should specifically point out where support can be found for any amendment made to the disclosure.

6. Claims 149-153 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear how one can generate 10,000 different unique combinations of 7 different compounds. Accordingly, one skilled in the art would not know how to interpret this limitation.

***New Rejections – Necessitated by Amendment***

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 89-148 and 154-156 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stylli et al. (US Patent 5,985,214) and Reddy (US Patent 6,017,908).

Stylli et al. teaches an automated method and system for identifying chemicals having useful activity such as biological activities of chemicals and collecting informations resulting from such a process (col. 6, lines 1-24). The method comprise of testing a therapeutic chemical for modulating activity of a target such as cell surface proteins in a cell based assay (col. 38, lines 46-67; col. 39, lines 1-9; col. 43, lines 6-9). The method comprise of dispensing the reagents (compounds) into the addressable sample wells, which contains a predetermined volume of the sample (test cells) (col. 6, lines 25-40; col. 8, lines 14-18). The chemical libraries are screened such that at least one chemical library of structurally related chemicals (col. 37, lines 44-51). Various method of detection of the compound interaction with the target includes

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fluorescent measurement such as FRET (fluorescence resonance energy transfer) (col. 27, lines 29-35; col. 28, lines 15-17; col. 39, lines 1-67 thru col. 42, lines 1-23).

The method of Stylli et al. does not expressly disclose that the chemical compounds tested are from the combination of at least seven different compounds.

Reddy disclose novel 3-epi vitamin D2 compounds from formula (I) and formula (II) (col. 2, lines 10-67 to col. 3, lines 1-35) that produce 266 vitamin D compounds, and the 'method of modulating a biological activity of a vitamin D-responsive cell' (col. 3, lines 40-44) to these novel 3-epi vitamin D2 compounds. 'The method involves contacting the cell with an effective amount of an isolated 3-epi vitamin D2 compound such that modulation of the activity of the cell occurs.' The method comprise of an in vitro assay using keratinocytes or parathyroid cells, or an assay similar thereto (e.g., differing in choice of cells, e.g., bone cells, intestinal cells, neoplastic cells) can be used to determine an "effective amount" of the 3-epi vitamin D2 compounds of formulas I and II, or combinations thereof.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the chemical compounds tested are from the combination of at least seven different compounds as taught by Reddy in the method of Stylli et al. One of ordinary skill in the art would have been motivated to include the chemical compounds tested are from the combination of at least seven different compounds in the method of Stylli et al. for the advantage of providing a rapid method to identify chemicals with useful activity at high throughput rates (Stylli: col. 1, lines 50-54) since both Stylli et al. and Reddy disclose method of modulating a biological activity of a cell with chemical compounds (Stylli: col. 38, lines 46-67; Reddy: col. 3, lines 40-44).

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct  
July 16, 2003

  
**ANDREW WANG**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**